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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,764

Applicant(s)

ALFERNES ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 18 September 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1 - 14 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 – 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Fawzi et al.

In reference to claim 1 and 14, Fawzi et al. discloses a constriction device (100) (Figure 1) that constricts body tissue comprising: an elongated sleeve with opposed open ends formed of expandable material (Col. 5, lines 57 – 60), when in an expanded condition receives body tissue, then when released from the expanded condition, constricts body tissue. The sleeve of the device disclosed by Fawzi et al., has a portion that is visible under X ray fluoroscopy (Col. 5, lines 60 – 66).

In reference to claims 2 – 11 and 13, the sleeve disclosed by Fawzi et al. includes an inner surface, an outer surface, and two opposed opened ends. By introducing the radio-opaque material into the woven braids (Col. 5, lines 60 – 64), the coating of X ray material will be embedded in the side wall, distributed throughout the sleeve on the outer as well as inner surfaces, the longitudinal dimension of the sleeve and adjacent to one of the opposed openings. Fawzi et al. also discloses the use of a plurality of strips in addition to introducing the radio-opaque material into the braids (Col. 5, lines 64 – 66).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness.

In reference to claim 1 and 14, Alferness discloses a constriction device (30) (Figure 4) that constricts body tissue in that it stultifies, or stops the outward expansion of the heart wall (Col. 3, lines 16 – 19) comprising: an elongated sleeve, in that the apex end diameter of the sleeve is small in respect to the length, with opposed open ends (31 and 32) formed of expandable material (Col. 3, lines 16 – 19), when in an expanded condition receives body tissue, then when released from the expanded condition, constricts body tissue. As shown in Figure 6, the expanded condition is considered by the examiner to be prior to inflation of inflatable member (54) (Col. 7, lines 22 – 28). The sleeve constricts the body tissue when the predetermined size of the sleeve is reduced (Col. 7, lines 25 – 28). The sleeve of the device disclosed by Alferness, has a portion that is visible under X ray fluoroscopy (Col. 5, lines 23 – 31).

In reference to claim 2, the sleeve disclosed by Alferness (Figure 3) includes an outer surface and a coating of X ray opaque material on the outer surface (25). The examiner has taken coating to mean “covering” (Merriam-Webster’s Collegiate Dictionary, 10th ed), and the markers (25) in Figure 3 cover the outer surface.

In reference to claim 3, the strips of X ray material disclosed by Alferness consisting of either platinum, titanium, or stainless steel wires (Col. 5, lines 29 – 31), are shown by Figure 3 to be along the longitudinal dimension of the sleeve.

In reference to claim 4, the sleeve disclosed by Alferness includes a side wall extending between the opposed open ends and X ray opaque material embedded in the side wall. The root of embedded, embed, has been taken by the examiner as “to make something an integral part of” (Merriam-Webster’s Collegiate Dictionary, 10th ed). This definition will carry through to the end of this action.

In reference to claim 5, the sleeve disclosed by Alferness has a side wall that defines a longitudinal dimension of the sleeve, and wherein the X ray opaque material comprises strips of X ray opaque material (Col. 5, lines 29 – 31) embedded in the side wall along the longitudinal dimension of the sleeve.

In reference to claim 6, Alferness discloses having the X ray opaque material on the inner surface of the sleeve. Col. 5, lines 24 – 27 reads, “the material of the [sleeve] can be made radio-opaque by inclusion of radio-opaque markers for identification of the outside surface of the heart...”. This implies placing the markers on the inner wall of the sleeve in order to be on the outside surface of the heart.

In reference to claim 7, the strips of X ray material disclosed by Alferness consisting of either platinum, titanium, or stainless steel wires (Col. 5, lines 29 – 31), are shown by Figure 3 to be along the longitudinal dimension of the sleeve.

In reference to claim 8, the sleeve disclosed by Alferness includes a plurality of X ray opaque elements (Col. 5, lines 53 – 55).

In reference to claim 9, Alferness shows the X ray opaque elements (25) adjacent to the opening (Figure 3).

In reference to claim 10, Col. 5 lines 53 – 57 teach that multiple markers can be distributed throughout the sleeve, and that by evaluating the markers in relation to each other, the performance of the tissue can be measured. Claim 10 states, “wherein the X ray opaque elements are arranged in a side-by-side relation”. Although Alferness did not specifically disclose this arrangement, it would have been obvious to one having ordinary skill in the art to place the elements in a side-by-side relation since this arrangement would have made it easy to visually see the displacement of the elements in relation to each other, therefore simplifying calculation of the heart’s performance.

In reference to claim 11, Alferness discloses having the X ray opaque elements on the inner surface of the sleeve. Col. 5, lines 24 – 27 reads, “the material of the [sleeve] can be made radio-opaque by inclusion of radio-opaque markers for identification of the outside surface of the heart...”. This implies placing the markers on the inner wall of the sleeve in order to be on the outside surface of the heart.

In reference to claim 12, Alferness discloses having the X ray opaque elements on the inner surface of the sleeve. However, he does not disclose the preferred method of attachment. It would have been obvious to one skilled in the art at the time the invention was made to attach the elements to the inner wall of the sleeve by some sort of adhesion.

6. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzalez et al. in view of Fawzi et al.

In reference to claims 15 and 16, Gonzalez et al. discloses a device (70, Figure 4) and method for suppressing leakage from body tissue by constriction comprising: providing an elongated sleeve formed from an expandable material (Col. 4, lines 44 – 58) and having opposed opened ends

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(72, 74), the sleeve being dimensioned and arranged to receive a portion of body tissue when in an expanded condition sufficiently to suppress leakage of at least one of body fluid and air, and drawing the body tissue into the sleeve to constrict the body tissue (Col. 4, line 59 – Col. 5, line 3). However, Gonzalez et al. fails to disclose including a material visible under x-ray fluoroscopy. It would have been obvious to one having ordinary skill in the art to modify the elongated sleeve disclosed by Gonzalez et al. to include radio-opaque material (Col. 5, lines 60 – 66) as taught by Fawzi et al. in order to locate proper positioning of the device by x-ray fluoroscopy.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF
December 2, 2002



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